



DOCKET NO.: 1.US2.CIP (AREN-0039)

PATENT

## IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re application of: Behan *et al.*

Serial No.: 09/060,188

Group Art Unit: 1646

Filed: April 14, 1998

Examiner: N. Basi

For: **A METHOD OF IDENTIFYING MODULATORS OF CELL SURFACE  
RECEPTORS USEFUL IN THE TREATMENT OF DISEASE**

**DECLARATION OF DR. DOMINIC BEHAN  
PURSUANT TO 37 CFR § 1.132**

I, Dr. Dominic Behan, being duly warned that willful false statements and the like are punishable by fine or imprisonment or both under 18 U.S.C. § 1001, and may jeopardize the validity of the patent application or any patent issuing thereon, state and declare as follows:

1. All statements herein made of my own knowledge are true and statements made on information or belief are believed to be true.

2. I am a co-founder and Vice President of Research at Arena Pharmaceuticals, Inc.

A copy of my *curriculum vitae* is attached as Exhibit 1.

3. I am an inventor of the above referenced patent application. I am familiar with the level of skill of those in the art of cellular biochemistry and molecular biology on April 14, 1997, which I am informed is the priority date of the above referenced patent application.

DOCKET NO.: 1.US2.CIP (AREN-0039)

PATENT

4. I have read the Office Action from the Patent Office dated November 11, 2002. I understand that there are several grounds of rejections at issue in the pending Office Action. I understand the Examiner to argue that the pending claims are "indefinite" in the usage of the terms "endogenous," "non-endogenous," and "endogenous sequence."

5. I believe that the assertions of the Examiner, described above, are incorrect. As of April 14, 1997, cellular biochemists and molecular biologists would have understood claims 61, 62, 69 and 70, and in particular, would have understood the definitions "endogenous," "non-endogenous," and "endogenous sequence." to be clear and definite.

6. The terms "endogenous" and "non-endogenous" were well known and were in common usage by cellular biochemists and molecular biologists on April 14, 1997. The patent application sets forth definitions of these terms on pages 18-19 which completely agree with the understanding of cellular biochemists and molecular biologists at this time.

7. The patent application states on pages 18-19 that:

ENDOGENOUS shall mean a material that a mammal naturally produces.

ENDOGENOUS in reference to, for example and not limitation, the term "receptor," shall mean that which is naturally produced by a mammal (for example, and not limitation, a human) or a virus. By contrast, the term NON-  
ENDOGENOUS in this context shall mean that which is not naturally produced by a mammal (for example, and not limitation, a human) or a virus. For example, and not limitation, a receptor which is not constitutively active in its endogenous form, but when manipulated becomes constitutively active, is most preferably referred to herein as a "non-endogenous, constitutively activated receptor." Both

**DOCKET NO.: 1.US2.CIP (AREN-0039)****PATENT**

terms can be utilized to describe both "in vivo" and "in vitro" systems. For example, and not limitation, in a screening approach, the endogenous or non-endogenous receptor may be in reference to an in vitro screening system. As a further example and not limitation, where the genome of a mammal has been manipulated to include a non-endogenous constitutively activated receptor, screening of a candidate compound by means of an in vivo system is viable.

From the context of the application, the common usage at the time, and from the definition provided above, practitioners in cellular biochemistry and molecular biology on April 14, 1997 would have understood that the term "endogenous" refers to a material (for example a nucleic acid or protein) that is produced by an organism in its natural state or its cell extracts, tissues or organs. That is, a material produced by a cell, cell extracts, tissue or organ of an organism in the absence of any external genetic manipulation. This would include any material encoded by the genome. Cellular biochemists and molecular biologists at the time also would have understood that the term "non-endogenous" refers to a material that is not produced by a cell, cell extracts, tissue or organ of an organism in question, for example a compound not produced by the organism in its natural state, or a material produced as a result of external genetic manipulation. These definitions were well understood by those of skill in the art on April 14, 1997, and are especially clear when taken in the context of the patent application.

8. Given that cellular biochemists and molecular biologists understood the definitions of "endogenous" and "non-endogenous," it is clear that as of April 14, 1997, cellular biochemists and molecular biologists would also have understood that the term "endogenous sequence," in

DOCKET NO.: 1.US2.CTP (AREN-0039)

PATENT

the context of a particular protein or nucleic acid, refers to a sequence of such protein or nucleic acid that is produced by an organism in its natural state or its cell extracts, tissues or organs.

9. I further declare that statements made herein of my own knowledge are true and that all  
5 statements made on information and belief are believed to be true; and further that these  
statements were made with knowledge that willful false statements and the like so made are  
punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States  
Code that such willful false statements may jeopardize the validity of the application or any  
patent issuing thereon.

10

Dated: 3-19-03By: 

Dr. Dominic Behan